UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES ONLY TO: **WAVE 1 CASES ON PLAINTIFFS' EXHIBIT A**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

RESPONSE IN OPPOSITION TO MOTION TO EXCLUDE TIMOTHY ULATOWSKI

In their Motion [Doc. 2060] and supporting Memorandum [Doc. 2065], Plaintiffs argue that Timothy Ulatowski should not be permitted to offer *any* opinions in these cases case because this Court has previously excluded evidence regarding the 510(k) process. *See In re C.R. Bard, Inc.*, 810 F.3d 913, 922 (4th Cir. 2016).

Mr. Ulatowski's opinion rests in part on FDA actions that have nothing to do with 510(k) clearance, and which go unmentioned in the Plaintiffs' memorandum. And his opinion also helps explain why this Court is wrong about the 510(k) process at issue in this case, which involves a different statute and a different type of predicate than the ones at issue in *Medtronic v. Lohr*, distinctions never presented to the Court in the *Bard* litigation and never addressed by it here.

This Opposition will first point out the grounds that do not involve 510(k), will explain why the Court's view of 510(k) as applied in these cases is mistaken, and will then address Mr. Ulatowski's challenged opinions.

This Opposition, like the Plaintiffs' motion, will confine itself to TVT-O. It should be noted, however, that even if TVT-O opinions were entirely excluded that would not justify striking his testimony in its entirety. For example, the centerpiece of Dr. Peggy Pence's opinion

is that Ethicon marketed Prolift in violation of federal law. *See* Ex. A, Expert Report of Peggy Pence at 105-06 (July 17, 2014), and Plaintiffs raise no objection to allowing Mr. Ulatowski to rebut that opinion if it is offered.

Relevant Regulatory History Aside from 510(k)

Classification of Surgical Mesh in 1988. In 1976, Congress set up the system the FDA uses to ensure the safety and effectiveness of medical devices. For efficiency, it told the FDA to use medical panels to classify types of devices according to their relative safety. Congress created three classes of medical devices: Classes I, II, and III. *See* 21 U.S.C. § 360c(a)(1)(A)-(C). Class I required the least evidence of safety and the least regulation. *See id.* § 360c(a)(1)(A). Class II fell in the middle, and Class III required the most. *See id.* § 360c(a)(1)(B)-(C).

Unlike the pacemaker lead at issue in *Lohr*, surgical mesh has been classified by medical panels. This took place 15 years before TVT-O was cleared.

Mr. Ulatowski discuses classification: "Classification is fundamental to FDA's regulation of medical devices." Ulatowski TVT-O Report at 15 [Doc. 2060-4, p. 16]. "In classifying the mesh the Classification panel and FDA evaluated the type of device's safety and effectiveness according to 21 CFR §860.84." *Id*. at 34 [Doc. 2060-4, p. 35]. He discusses the regulation of PROLENE suture and points out that classification of surgical mesh afforded the FDA an opportunity to examine the filaments in mesh form:

> Besides the approved [New Drug Application] discussed above, FDA had a major opportunity to assess the safety and effectiveness of PROLENE when it classified surgical mesh. … In classifying surgical mesh the Panels relied upon their clinical experience with mesh, their review of published clinical data, and there assessment of the risks posed by mesh to healt as stipulated in the act regarding classification procedures…
>
> Classification of the mesh by FDA into Class II established that under the law

> reasonable assurance of safety and effectiveness of surgical mesh would be based upon general controls, for example, 510(k) submission, and any special controls the FDA may finalize for the mesh.

Id. at 60-61 [doc. 2060-4, pp. 61-62]. The Plaintiffs' Memorandum makes no mention of this element in Mr. Ulatowski's report and does not give any reason for excluding it.

2011 Advisory Committee Meeting and 2013 FDA statement. Eight years after TVT-O was cleared, the FDA convened a special medical advisory committee meeting to examine surgical mesh products. From 1992 to 2010, the FDA cleared 168 pelvic mesh devices. *Id*. p. 40 [Doc. 2060-4, p. 41]. In 2011, its Obstetrics and Gynecological Panel reviewed a summary of medical literature and reported complications associated with mesh. The panel also heard testimony and took public comment. *Id*. at 43-44 [Doc. 2060-4, pp. 44-45]. In 2013, the FDA then issued this statement:

> For SUI, both the panel and the FDA's review found that: The safety and effectiveness of multi-incision slings is well-established in clinical trials that followed patients for up to one year. Longer follow-up data is available in the literature, but there are fewer of these long term studies compared to studies with one-year follow-up.

Id. at 44 [Doc. 2060-4, p. 45]. That statement remains on the FDA website today. It was made after consideration of 168 pelvic mesh devices and medical panel review. It is not tied to the 510(k) for any one device. There is nothing like this in *Lohr*.

The TVT-O 510(k)

In 2003, the FDA cleared TVT-O based on reasonable assurance that it was as safe and effective as its predicate, TVT, a Class II device. *Id*. at 62, 76-80 [Doc. 2060-4, pp. 63, 77-81]. The governing statute for Class II devices allowed clearance based on equivalence to a device "classified in class I or II." 21 U.S.C. §360c(f)(1)(A). In other words, TVT-O's predicate was *not* a pre-1976 unregulated device but was, instead, a device *classified* based on the work of the

medical panels leading up to the 1988 classification decision. Not only that, but the FDA had been responsible for changes to the TVT label, which were carried over to TVT-O, and during the interim TVT had been subject to FDA monitoring. Ulatowski TVT-O Report pp. 63-64 [Doc. 2060-4, pp. 64-65].

Ulatowski quotes from the FDA as follows:

> Generally, predicate devices, as largely class II devices, are those for which there is a reasonable assurance of safety and effectiveness with general and applicable special controls….
>
> When a predicate has a well established risk/benefit profile and is generally well regarded by the healthcare community, a premarket comparison of a new device to that predicate, with sufficient information, can provide reasonable assurance that the device, subject to general and applicable special controls, is safe and effective for its intended use.

Id. at 85 (emphasis Ulatowski's) [Doc. 2060-4, p. 86]. As the Supreme Court said in *Food and Drug Administration v. Brown & Williamson Tobacco Corp*., 529 U.S. 120 (2000), the Supreme Court discussed the medical device classification system and stated that "[r]egardless of which category the FDA chooses, there must be a reasonable assurance of the safety and effectiveness of the device." *Id*. at 134; *see also* 21 U.S.C. § 360c(a)(1)(B) (classification of medical devices is to provide "reasonable assurance of the safety and effectiveness" of the device).

There was no such classification of the predicate at issue in *Lohr*, a case with an archaic history which has little to say about the 510(k) process as it now operates for Class II devices.

The device at issue in *Lohr*—a pacemaker lead— had never been classified by the FDA. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478 n.3 (1996) (FDA may reclassify "at some time in the future"). Under the 1976 Act, because it had not been classified by the FDA it was automatically in Class III. It was allowed to be sold because Congress, as a matter of expediency, had said that Class III devices could be sold if they were equivalent in safety and effectiveness to devices

legally marketed before May 28, 1976. In other words, it was "grandfathered." *See* 21 U.S.C. § 360e(b)(1)(B) (separate statute for Class III devices). So it was correct for the Supreme Court to say, as the Court in *Lohr* did, that the device's safety had not been "formally reviewed" in the section 510(k) process. *Lohr*, 518 U.S. at 493.

But that was not what happened here. Surgical mesh was classified based on its safety, and TVT-O was shown to be equivalent to other surgical mesh and placed in Class II. As the agency has stated, "*classification* of a new device through the 510(k) process requires FDA to determine the issues of safety and effectiveness presented by the new device, and the regulatory controls necessary to address those issues."[1] *See also Brown & Williamson*, 529 U.S. 120 at 142.

None of this was called to the attention of this Court in its initial encounter with the FDA and pelvic mesh, *In re C.R. Bard Inc.*, 810 F.3d 913, 920-21 (4th Cir. 2016). Nor was it before the courts in the other cases on which Plaintiffs rely.

ARGUMENT

Plaintiffs' Memorandum largely relies on Fed. R. Evid. 403, but it fails to discuss either the probative value of FDA evidence, or the positive role experts can play in presenting it.

As RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY §4(b) provides:

> [A] product's compliance with an applicable product safety statute or administrative regulation is properly considered in determining whether the product is defective with respect to the risks sought to be reduced by the statute or regulation, but such compliance does not preclude as a matter of law a finding of product defect.

The Ulatowski TVT-O report establishes that Ethicon has complied with the FDA statute and regulations designed to provide reasonable assurance of the safety and effectiveness of medical devices. The common law of 35 states is at issue in this Wave 1 proceeding, and, for the purpose

[1] Ex. B, FDA, The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]: Guidance for Industry and Food and Drug Administration Staff at 3-4 (July 28, 2014) (emphasis added).

of this motion, it must be assumed that at least some of them agree with the RESTATEMENT. *See, e.g., Miller v. Warren*, 390 S.E.2d 207, 209 (W. Va. 1990). And several of the legislatures of those states have created a rebuttable presumption for compliance with government regulations. *See e.g.* Colo. Rev. Stat. Ann. § 13-21-403(1); Fla. St. Ann. § 768.1256; Ind. Code § 34-20-5-1; Tenn. Code Ann. § 29-28-104(a); Tex. Civ. P. & Rem. § 82.008; Utah Code Ann. § 78B-6-703(2); Wis. Stat. § 895-.047(3)(b).

Plaintiffs wrongly belittle the relevance of FDA evidence and seek to persuade the Court that it is too complex for a jury to consider. But many of the alleged complexities are of their own making. Their attack on the use of 510(k) for Class III devices, the issue in *Lohr*, has no place here where there was no "grandfathering." Any possible claim that Ethicon failed to provide information to the FDA is now moot because the 2011 Advisory Committee process not only combed the literature and medical device reports, but also took into consideration the FDA's experience in regulating 168 pelvic mesh devices. And the wisdom of Congress' decision to entrust the FDA with making safe and effective devices available is not for a jury to reconsider. *Horn v. Thoratec Corp.*, 376 F.3d 163, 179 (3d Cir. 2004)

Finally, it has long been recognized that expert testimony is an efficient way to present regulatory evidence to a jury. Official pronouncements of a federal agency charged with protecting the public health, if relied on by an expert, are admissible as providing some evidence of the safety and effectiveness. *See Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 163 (1988) (factual findings in government reports admissible); *Ellis v. Int'l Playtex, Inc.*, 745 F.2d 292, 301-02 (4th Cir. 1983) (federal and state findings on toxic shock published by FDA and CDC admissible); *Musgrave v. Breg, Inc.*, 2011 WL 4502032, *6 (S.D. Ohio Sept. 28, 2011) (FDA bulletins admissible under Rule 803(8)).

In re Mirena IUD Products Liability Litigation, 2016 WL 890251 (S.D.N.Y. Mar. 8, 2016), recently collected opinions in which courts had admitted "expert testimony regarding companies' compliance with FDA regulations." *Id* at *46. It explained: "Admitting expert testimony in this context makes sense given the complicated nature of FDA regulations, and it would be helpful to the jury to have an expert explain this complex regulatory process." *Id*. The court, however, instructed the parties to propose an instruction that the jury should "determine the outcome based on the law as I give it to them, not on the legal views of a witness." *Id*.

In fact, there is no other way to present FDA evidence. The agency itself cannot be deposed and will not testify.

I. Mr. Ulatowski's qualifications and opinions.

Several of Plaintiffs' arguments relate to Mr. Ulatowski's qualifications. Mr. Ulatowski's opinions are reliable and supported by his knowledge and training about the section 510(k) process, postmarket surveillance, enforcement actions, and design controls that he has accumulated over 37 years at the FDA. During his tenure at the FDA, Mr. Ulatowski held multiple positions with increasing levels of responsibility. In 2003 when TVT-O was cleared, he was Director of Compliance at the FDA's Center for Devices and Radiological Health. Ex. C, Ulatowski 8/12/13 Dep. 20:19-21.

During his deposition, Mr. Ulatowski made clear that some of his opinions have limits. For example, he is not a physician and does not intend to delve into medical opinions related to urogynecology. *See* Ex. D, 11/29/12 Ulatowski Dep. at 91, 199-200, 202. This did not disqualify him from working at the FDA and does not disqualify him here. If it did, it would also disqualify Plaintiffs' regulatory expert Peggy Pence, who not only is not a doctor but never worked at the FDA. Mr. Ulatowski's opinions are admissible.

Plaintiffs have moved to exclude Mr. Ulatowski's opinions because they "relate directly

to FDA issues," using Ulatowski's TVT-O opinions as examples. [Doc. 2065, pp. 5-6]. Ethicon will address each of the arguments in the order presented by Plaintiffs:

1. Opinion # 1 – Recall of ProteGen by its manufacturer. Ethicon does not intend to introduce evidence of the manufacturer's decision to stop selling ProteGen, which is irrelevant here, and intends to move to exclude that evidence. If, however, the Court denies the motion and Plaintiffs are allowed to offer evidence of the recall, Mr. Ulatowski should be allowed to testify that the defects in ProteGen which caused its manufacturer to take it off the market do not exist in these devices and that the FDA never took any enforcement action against Ethicon based on ProteGen's recall. *See* Ulatowski TVT-O Report at 57-59 [Doc. 2060-4, p. 58-60].

2. Opinion # 2 - Prolene safety and effectiveness carried over to mesh. Plaintiffs wrongly challenge Mr. Ulatowski's opinions concerning the FDA's continued findings of established safety and effectiveness of the Prolene material. This is not a 510(k) matter and involves events that took place a dozen years before TVT-O's 510(k) was submitted. It is evidence that has to do with the approval of suture and classification of surgical mesh made of the same filaments as suture, not 510(k) clearance of a device. *See Cisson, et al. v. C.R. Bard, Inc.*, 2013 WL 3821280, *7 (S.D. W. Va. July 23, 2013).

Prolene approved labeling is relevant because some of its words were carried over and formed the basis for TVT-O labeling. Ulatowski TVT-O Report, p. 34 [Doc. 2060-4, p. 35]. Also this evidence is relevant given Plaintiffs' contention that when the filaments are made into mesh they become unsafe. *See Lewis v. Johnson & Johnso*n, 991 F. Supp. 2d 748, 758 (S.D. W. Va. 2014). The FDA found no such distinction when it placed all surgical mesh in Class II in 1988. That supports Ethicon's belief that the quantity of filament does not matter.

3. Opinion #3 - 510(k) clearance needed for design changes. This opinion is relevant

in any case where plaintiffs claim that there is a safer alternative design to TVT-O because any such design is not, as a matter of law, "available" if it would have to be cleared by the FDA but has not been cleared. *Militrano v. Lederle Labs*, 769 N.Y.S 2d 839, 852 (N.Y. Sup. Ct. 2003). It is also relevant to show that Plaintiffs' design defect claims are barred by impossibility or conflict preemption, a contention this Court has rejected. *See Mullins v. Ethicon, Inc.*, No. 2:12-CV-02952, 2015 WL 7761033, at *6 (S.D. W. Va. Dec. 2, 2015); *but see Yates v. Ortho-McNeil-Janssen Pharms., Inc*., 808 F.3d 281, 298-300 (6th Cir. 2015) (decided 9 days after *Mullins*).

4. Opinion #4 - FDA has not required labeling changes. The Plaintiffs' suggestion that this evidence would imply FDA "approval" gets things backwards.

When the FDA classifies devices, it classifies the safer devices into Class II, which allows them to be marketed through "clearance." It is only the more risky devices which are placed in Class III where "approval" is required. So in the ordinary case today "clearance" signifies *safety*, and "approval" signifies *risk*. There is no reason for a manufacturer whose device can be marketed through clearance because of its inherent safety to want to claim that it in fact is so risky that it should have gone through an approval process.

The fact that the FDA required changes in labeling in 1998 before it cleared TVT, and then cleared the same language without change when it cleared TVT-O in 2003, and then did not require any further changes after the comprehensive 2011 review, is some evidence that TVT-O's labeling is consistent with both safety and effectiveness.

5. Opinion #5 - Patient brochures do not replace informed consent process. This opinion is in response to an assertion by Plaintiffs that patient brochures should inform patients of all the risks of gynecological surgery. Mr. Ulatowski's opinion is that no such duty is imposed by the FDA and, in fact, the FDA regards brochures as merely being "supplemental to

physician interaction." Ulatowski TVT-O Report, p. 65 [Doc. 2060-4, p. 66]. In any case where a patient brochure is at issue, it is directly relevant for the jury to hear an explanation of what how patient brochures function in the industry and their purpose. *See* Fed. R. Evid. 401. It is therefore not a waste of time, and this straightforward opinion will not confuse the jury.

6. Opinion #6 - Requirements for brochures. This opinion also rebuts Plaintiffs' claim, in that it points out that "there is no medical device statutory or regulatory provision concerning 'fair balance' prescription of over-the-counter device labeling or advertising" like there is in drug regulations. *Id*. at 68; *cf.* Ex. E, Pence TVT Report, p. 15 (claiming there is a fair balance requirement for brochures). This opinion also points out that certain statements in Ethicon brochures, such as the phrase "minimally-invasive," are found in FDA literature and professional association statements. This is relevant to rebut the claim that this phrase is not true. None of this testimony requires medical expertise.

7. Opinion #7 - The TVT-O's manufacture. If a plaintiff should claim a manufacturing defect, and at least one has, then this opinion is admissible to show that the FDA's records and TVT-O issue reports do not show any evidence of such a defect being reported.

In any claim involving manufacturing defect, the existence of FDA Warning Letters based on inspection observations and issue reports of malfunctions will be highly probative. As described by Mr. Ulatowski "[c]omplaint trends may identify manufacturing nonconformities that require corrective and preventive action." Ulatowski TVT-O Report, p. 70 [Doc. 2060-4, p. 71]. Based on his extensive expertise in the field with these types of documents, Mr. Ulatowski is highly qualified to examine them to identify the existence of any trend or complaint indicating a manufacturing nonconformity.

8. Opinion #8 - Complaint and medical device reporting procedures. This opinion of Mr. Ulatowski is entirely defensive in nature. Ethicon intends to move to exclude any evidence of medical device reports, which are recognized as being unreliable hearsay. It also intends to move to exclude any claim that Ethicon did not comply with medical device reporting requirements. If these motions are unsuccessful and Plaintiffs are allowed to put on medical device report evidence, Mr. Ulatowski should be allowed to testify about the limitations on those reports and Ethicon's compliance with FDA requirements.

9. Opinion #9 - Issue Report and MedWatch reports. Ethicon will not introduce evidence that Ethicon complied with FDA regulations in the submission of Medwatch reports if the Court excludes Plaintiffs' experts' opinions that they did *not* comply with regulations with respect to the same. *See, e.g.*, Ex. F, Pence TVT-O Report, p. 136 (stating "MDR reports for MDR-reportable events were not submitted to FDA as required by 21 CFR Part 803, Subpart E").

10. Opinion #10 - Pre-market requirements for TVT-O. This testimony is also defensive in nature. If and only if Plaintiffs are allowed to allege that Ethicon failed to conduct proper testing before marketing TVT-O or otherwise did not comply with FDA 510(k) requirements, Mr. Ulatowski should be allowed to rebut their claims.

In addition to the regulations, in his report, Mr. Ulatowski identified ISO 14971 as a recognized industry standard for the assessment of risk. Ulatowski TVT-O Report, p. 79 [Doc. 2060-4, p. 80]. He opined that it is "an FDA recognized standard for assessment of risk and a basis for industry risk management practices" and that the Ethicon design safety assessment complied with that standard. *Id.* In addition, in his deposition Mr. Ulatowski cited ISO standard for 10993 as an industry standard for testing biocompatibility before marketing a device. Ex. G,

6/2/15 Dep. 53:6-12, 55:5-56:10. Plaintiffs have not challenged the reliability of these sources as a support for Mr. Ulatowski's opinions.

Nor do Plaintiffs challenge Mr. Ulatowski's qualifications to determine whether Ethicon's pre-market analysis met the industry standard of care. In his career at the FDA working for 25 years in device evaluation, Mr. Ulatowski participated in hundreds of health risk assessments. Ex. G, Ulatowski 6/2/15 Dep. 122:5-17. Again, he does not opine from the perspective of a clinician with direct experience in managing patient care, but rather as a regulatory expert who understands the industry standards for placing devices on the market, a standard Plaintiffs' experts opine was not met.

11. Opinion # 11 - TVT-O labeling. A principal question in this litigation is what the law requires Ethicon to say about adverse events in its IFU and other labeling. Mr. Ulatowski's opinion is that the "labeling is not intended to be a textbook of gynecological surgery." Ulatowski TVT-O Report, p. 82 [Doc. 2060-4, p. 83]. And he quotes from a regulation which provides that relevant hazards, contraindications, side effects and precautions "may be omitted from dispensing package if, but only if, the article is a device for which directions, hazards, warnings and other information are commonly known to practitioners licensed by law to use the device." *Id*. at 28 [Doc. 2060-4, p. 29]. And he points out that the TVT-O IFU further says that it is to be used by surgeons "trained in the treatment of stress urinary incontinence." *Id*. at 82 [Doc. 2060-4, p. 83].

In fact, his opinion goes further and specifies what the FDA says such surgeons "commonly know," which is everything except mesh erosion:

> The most common complications reported through MDRs for surgical mesh slings for SUI repair, in descending order of frequency, include: pain, mesh erosion through the vagina … infection, urinary problems, recurrent incontinence, paid during sexual intercourse (dyspareunia), bleeding, organ perforation, neuro-

> muscular problems and vaginal scarring…. With the exception of mesh erosion, the above complications can occur following a non-mesh surgical repair for SUI.

Id. p. 45 [Doc. 2060-4, p. 46]. And he points out that as early as 2008, the FDA told practitioners in a public health notice that they should "inform patients that implantation of surgical mesh is permanent, and that come complications associated with the implanted mesh may require additional surgery that may or may not correct the complication." *Id*. p. 42 [Doc. 2060-4, p. 43].

All of this is relevant to justify Ethicon's assumptions about what surgeons "commonly know," to support the adequacy of Ethicon's warnings, and lay a foundation for its belief that its warnings were adequate in the face of plaintiffs' contentions to the contrary. None of this requires that Mr. Ulatowski himself be a physician in order for him to testify to what the FDA has said and done.

12. Opinion # 12 – Appropriate risk management policies. With respect to regulatory compliance, Ethicon will not introduce evidence of compliance with the regulations if the Court excludes Plaintiffs' experts' opinions that they did *not* comply with regulations.

If the Court should allow plaintiffs' experts to invoke ISO standards, Mr. Ulatowski opines that Ethicon has complied with International Standards Organization Standard 14971:2007, which as Mr. Ulatowski described in his report, is "commonly utilized to develop the processes and procedures associated with risk management activities" and has been recognized by the FDA. Ulatowski TVT-O Report, p. 13-14 & n.15 [Doc. 2060-4, pp. 14-15]. Mr. Ulatowski described this standard in detail in his Report. *Id.* at 14-15 [Doc. 2060-4, pp. 15-16].

13. Opinion # 13 - the 510(k) review includes an analysis of the safety and effectiveness of the device. As explained above, because TVT-O was found to be equivalent in

safety and effectiveness to TVT and other surgical mesh, which had been placed Class II after a medical panel review found a history of safety and effectiveness, there is no doubt that the 510(k) clearance was based on a finding of safety and effectiveness. It was cleared in the way Congress wanted devices to be cleared, and was not cleared based on makeshift pre-1976 grandfathering like the device in *Lohr*. Mr. Ulatowski emphasizes the critical role Class II classification plays in the safety and effectiveness determination. *Id*. p. 86 [Doc. 2060-4, p. 87].

14. Opinion #14 - Explanation for increase in MDRs after 2011. Ethicon will not introduce this opinion if the Court excludes evidence of medical device reports as Ethicon will request in motions in limine and if it excludes Plaintiffs' regulatory opinions concerning such reports. *See, e.g.*, Ex. H, Pence Supplemental TVT-O Report, p. 8 (citing "a current overview of the results of MAUDE database searches for total number of medical device reports from 1999 through 2015 for Ethicon and a number of competitor surgical mesh devices marketed for the repair of SUI and POP"). However, if this testimony is admitted, Mr. Ulatowski's opinions explaining the reason for the surge in case reports is proper. Plaintiffs have not challenged his qualifications or the reliability of this opinion.

15. Opinion # 15 – No need to clear laser-cut mesh. This testimony is also defensive in nature. If Plaintiffs are allowed to argue that Ethicon should have cleared laser cut mesh even though it is not clinically different from mechanically-cut mesh, then Mr. Ulatowski should be allowed to rebut that testimony. Ex. I, Parisian TVT-S Report, p. 44 (criticizing Ethicon for not adequately informing FDA of change to laser cutting of mesh).

CONCLUSION

For these reasons, Plaintiffs' Motion to Exclude the Opinions and Testimony of Timothy Ulatowski [Doc. 2065] should be denied. Plaintiffs offer no reason for not allowing him to tell

the jury about the regulatory history of suture, the classification of surgical mesh in 2008, and the 2011 Advisory Committee and the 2013 FDA statement, none of which have anything to do with 510(k). They also offer no reasons to exclude defensive testimony with respect to the history of Prolift or other non-TVT-O devices. Finally, their attack on the 510(k) process as applied in this case is misplaced, and their other challenges are, in any event, premature because the need for Mr. Ulatowski's evidence will depend on what the Plaintiffs claim in individual cases.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on this day, I electronically filed this document with the Clerk of the Court using the CM/ECF system which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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